

RFA Meeting:
**Testing Interventions to Improve Adherence
to Pharmacological Treatment Regimens**

***Improving Medication Adherence In
Co-morbid Conditions***

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Aims

- 1) To Evaluate an Intervention Developed Within a Problem-Solving Framework in a Sample on Multiple Pharmacological Therapies for Co-Morbid Conditions**
- 2) Explore the Cost Effectiveness of Improving Adherence With This Intervention**
- 3) Examine Temporal Variation in Adherence Among Good Adherers to Multiple Pharmacological Treatment for Co-morbid Conditions**

Efficacy of Intervention on Single Medication for Single Condition - Rheumatoid Arthritis

Difference in Change Scores Post Treatment

$t = 1.71, p \leq .045$

Effect Size = 0.37

**Changes in Adherence Were Associated
With Changes in Pain**

$r_s = -.29, p = \leq .01$

Theoretical Basis: Problem Solving

- ◆ **Process of Developing Coping Strategies for Everyday Living**
- ◆ **Designed to Train Individuals in Procedures That Promote Independence in Management of Day to Day Problems As Well As Generalization**
- ◆ **Skills Include: Data Collection, Identification of Problems, Generation and Testing of Strategies, Revision**

Targeted Sample

- ◆ **Persons Aged 40 or Over on Pharmacological Treatment for Type 2 Diabetes and Either Hypertension or Hyperlipidemia or Both**
- ◆ **198 *Poor* Adherers**
(Adherence $< 80\%$ by Electronic Monitor)
- ◆ **198 *Good* Adherers**
(Adherence $\geq 80\%$ by Electronic Monitor)

Design

Intervention study

**RCT With Six Months of Intervention and Six
Months of Maintenance**

Observational study

12 Months of Observation of Adherence

Overview of Research Plan

Recruitment/Eligibility Screening

Consent

Baseline: Adherence Assessment
Paper/Pencil Assessment
Clinical Outcome Assessment
Cognitive Assessment

Good Adherers

Good Adherers Observation

t² (6 mo) 6 month Assessment

t³ (12 mo) 12 Month Assessment

Poor Adherers

Randomize

Intervention

Usual Care

(6 Month) Post Intervention Assessment

Randomize

Maintenance Intervention

Observation

(12 Month) Post-Follow Up Assessment

Intervention

**12 Bi-Weekly Telephone Calls Focused
on a Particular Topic**

Maintenance

**Randomized To Three Months of Faded Booster
Sessions + Three Months of Observation or to Six
Months of Observation**

Data Collection

Baseline.....Six Months (Post Intervention)....

12 Months (Post Maintenance Setting:

GCRC or Equivalent

Predictor and Outcome Data

Adherence (Ardex Electronic Pill Monitor)...
Continuous for 12 months

**Clinical Outcome: Lipid Profile, HbA1c, Blood
Glucose, Insulin, Blood Pressure**

**Subject Data: Sociodemographic Profile, Self-
Reported Adherence, Costs of Treatment,
Physical Symptoms, Diabetes History**

Predictor and Outcome Data

Moderator Variables:

- **Depression (Beck Depression Inventory)**
- **Anxiety (Spielberger State-Trait Anxiety Inventory)**
- **Problem Solving (Problem Solving Inventory)**
- **Symptoms (Symptom Distress Scale)**
- **Functional Status (Jette Functional Status Inventory; 6-minute walk)**
- **Perceived Treatment Efficacy (Perceived Therapeutic Efficacy Scale)**
- **Social Support (Interpersonal Support Evaluation List)**
- **Co-Morbidity (Study based questionnaire derived from the Charlson Co-Morbidity Index)**
- **Neuropsychological Assessment (memory, attention emphasis)**

Recruitment

- ◆ **Active Recruitment: Strategies Have Varied As the IRB Has Altered Its Approved Strategies From Time to Time**
- ◆ **A:**
 1. **Physician Offices: ID Patients Through Electronic Data Base - MD Letter to Patient Introducing Study - Study Call to Nonrefusers**
 2. **Physician Offices: Poster + Brochures - MD Point Out to Patients - Patients**
 3. **Physician Offices: Posters + Brochures - Patients Mail Tear off to Study - Call Patients**
 4. **Physician Offices: Return to Strategy 1**

Recruitment

- ◆ B:
 1. Community: Ads in Neighborhood Papers
 2. Community: Booths at Health Fairs and Other Events
 3. Pharmacy Brochure Stands
 4. Community: Working With Minority Health Center to Expand Community Recruitment
- ◆ C:
 1. Mailings From Diabetic Supplies Mailing Service
 2. Mass Mailings From Registers
(Lists Include 15,200 Names)
 3. Exploring Mass Mailings With Health Plan

Recruitment Status

- ◆ **57 Enrolled**
 - **14 Good Adherers**
 - **27 Poor Adherers**
 - **16 Pending Group Assignment**
- **14% Minority**
- **67% White**
- **19% Pending Status**

Source of Subjects

- ◆ 61% Physician Offices
- ◆ 26% Community Brochures
- ◆ 2% Advertisements

Major Issues/Problems

- ◆ **IRB Process**
- ◆ **Changing Guidelines for Recruitment**

Timeline

Sept 00	Approval
Jan 01	Funding Received
Jan - May	Hire Project Manager & Graduate Student Assistant Revise Intervention and Education Materials for Diabetes
May 01	Submit Protocol to GCRC
Dec 01	Final Approval From IRB After GCRC and Geriatric Scientific Committee Reviews
Mar 02	Initial List of Patients From Recruitment Site 1 Were Received and Recruitment Began
	Throughout 02 and 03 Numerous Changes in Approved Recruitment Strategies Were Announced Requiring Protocol Modifications and Re-establishment of Recruitment Procedures Within Sites
	Identified a Failure to Treat Hyperlipidemia Among the Majority of Persons

Timeline

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|----------------|--|
| July 03 | DSMB Telephone Conference to Address Recruitment Issues. Modification in Criteria to Facilitate Enrollment - Patients Must Have Two of the Three Target Conditions Being Treated With Pharmacotherapy – Recommendations for Mass Mailings |
| July 03 | Modifications Approved by IRB With an Expansion of Recruitment Strategies |
| Sept 03 | Reintroduce Initial Physician Office Recruitment Purchase Mailing Lists |
| Oct 03 | Initiate Mass Mailings |

The Future

- ◆ Recruitment Has Picked Up
- ◆ \$\$ Savings Will Allow for a One-Year Extension to Complete the Study

